



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0405]

Stephen C. Delaney, Jr.: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Stephen C. Delaney, Jr. for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Delaney was convicted of one felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Delaney was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of August 10, 2012 (30 days after receipt of the notice), Mr. Delaney had not responded. Mr. Delaney's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade,
Office of Regulatory Affairs,
Food and Drug Administration,
12420 Parklawn Dr.,
Rockville, MD 20857,
301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On April 8, 2011, Mr. Delaney was convicted in the U.S. District Court for the District of Massachusetts of one count of false labeling under the Lacey Act in violation of 16 U.S.C. 3372(d).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the importation into the United States of any food. The factual basis for this conviction is as follows: As alleged in the indictment that was filed against Mr. Delaney, he was the president and owner of a seafood packing and re-packing company. On or about April 15, 2009, in violation of 16 U.S.C. 3372(d), he knowingly made and submitted a false record, account and label for, and a false identification of fish that had been and was

intended to be, imported, purchased, and received from a foreign country and transported in interstate commerce, and involved the sale and purchase, the offer of sale and purchase, and the intent to sell and purchase, fish with a market value of approximately \$8,000. Specifically, Mr. Delaney falsely labeled imported frozen fillets of pollock, product of China, as cod loins, product of Canada.

As a result of his conviction, on July 9, 2012, FDA sent Mr. Delaney a notice by certified mail proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Delaney was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food because he knowingly made and submitted a false record, account and label for, and a false identification of fish that had been and was intended to be, imported, purchased, and received from a foreign country and transported in interstate commerce, and involved the sale and purchase, the offer of sale and purchase, and intent to sell and purchase, fish with a market value of approximately \$8,000.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act (21 U.S.C. 335a(c)(3)), that Mr. Delaney should be subject to a 5-year period of debarment. The proposal also offered Mr. Delaney an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Delaney failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR Part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. Stephen C. Delaney, Jr. has been convicted of a felony under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Delaney is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Delaney is a prohibited act.

Any application by Mr. Delaney for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0405 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 2012.

Armando Zamora,
Acting Director,
Office of Enforcement,
Office of Regulatory Affairs.

[FR Doc. 2012-24528 Filed 10/04/2012 at 8:45 am; Publication Date: 10/05/2012]